

## **REMARKS/ARGUMENTS**

### **The Status of the Claims.**

Claims 1-3, 5-16, and 20-24 are pending with entry of this amendment. Claims 4 and 17-19 have been cancelled, and claims 3, 7-9 and 13-16 are withdrawn from current consideration. Claims 1 and 23 are amended herein. These amendments introduce no new matter and support is replete throughout the specification. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter or agreement with any objection or rejection of record.

With respect to claims 1 and 23, support for identifying an individual in need of immune response modulation can be found throughout the specification. For example, see specification at paragraphs 33, 43, 108, 111, and the section entitled "Immunomodulation in Treatment of Diseases and Other Ailments" starting at paragraph 113.

Applicants submit that no new matter has been added to the application by way of the above Amendment. Accordingly, entry of the Amendment is respectfully requested.

### **Interview Summary**

Applicant interviewed by phone with Examiner Shengjun Wang on January 30, 2007, regarding the present application. Claims discussed included independent claims 1 and 23. Prior art discussed included U.S. patent 6,001,555 to Henderson and U.S. patent 4,378,364 to Grassetti.

Examiner Wang agreed that proposed amendments (essentially as amended herein), provided in a fax of January 22, 2007, would avoid anticipation by the Henderson patent. The Examiner offered that induction of a feeling of well-being in the Grassetti patent from administration of 6,6'-dithiondinicotinic acid may inherently result from immune modulation. Applicant noted that this is not necessarily the case.

### **35 U.S.C. §102.**

Claims 1-2, 5-6, 10-12, and 20-24 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Henderson (US 6,001,555) and also by Grassetti (US 4,378,364). Applicants traverse.

In order for a reference to anticipate an invention, the reference must teach each and every element of the claimed invention. That is, in order for a reference to anticipate an invention, anticipation requires that "all limitations of the claim are found in the reference, or 'fully met' by it." Kalman v. Kimberly-Clark Corp., 218 USPQ 781, 789 (Fed. Cir. 1983).

**Henderson does not inherently teach the claims.**

Henderson describes how certain compounds can inactivate retroviruses by attacking CCHC zinc fingers of the viral nucleocapsid. The Action alleges, in section 3, that Henderson "discloses the treatment of retroviruses including lentivirus and oncovirus, with disulfides, such as 6,6'-dithiondinicotinic acid." However, this is incorrect. At the cited section J of Henderson "Administration of compounds in vivo", "those compounds which inactivate retroviruses, as determined by the methods described herein, can be used to treat retrovirally-mediated diseases..." However, careful reading of Henderson shows that, e.g., at Table 2 "Disulfide Reagents" 6,6'-dithiondinicotinic acid is not shown to inactivate the virus (see Protein (virus) column associated with abolition of infectivity in the text starting at column 20, line 53). That is, 6,6'-dithiondinicotinic acid is not shown in Henderson to be a compound determined by the methods to inactivate retroviruses, so it is not taught as useful to treat retrovirally-mediated diseases according to Henderson's own statement. Moreover, because the present claims are further limited to administration to other than those infected with a retrovirus, Henderson is irrelevant.

With regard to the argument at section 4 of the action concerning limitations of the preamble, Applicants believe *Kropa* requires the limitations of the preamble "modulating an immune response" to be considered in construction of the claim. For example, claims 10-12, cited in the Action, at least depend on the preamble for completeness. However, the point is moot because the current amendments to the method include "identifying an individual in need of immune response modulation", "thereby modulating the immune response." Because Henderson does not teach identifying an individual in need of immune response, not all limitations are taught and additional reasons exist to withdraw the rejection. Because Henderson does not teach modulating the immune response of an

individual not infected with a retrovirus, not all limitations are taught and still additional reasons exist to withdraw the rejection.

Because the cited reference does not include all limitations of the independent claim, it is not anticipated, nor are any of the associated dependent claims anticipated.

With regard to claims 2, 5, 6, 10, 11, and 12, the Action fails to state a *prima facie* case. No attempt is made in the Action to allege a teaching of the particular immune responses of the claims in Henderson. Indeed, no such teachings exist in Henderson. Therefore additional reasons exist to withdraw the rejection of these dependent claims.

With regard to claims 20-22, the Action fails to even attempt to state a case. The Office must present a case, providing notice of the rejection basis or rejections must be withdrawn.

With regard to claim 23, as discussed above, 6,6'-dithiondinicotinic acid is not shown in Henderson to be a compound determined by the methods to inactivate retroviruses, so it is not taught as useful to treat retrovirally-mediated diseases according to Henderson's own statements at column 13, line 51. Therefore the limitations of the claim are not taught in Henderson and the rejection must be withdrawn. As dependent claim 24 includes all the limitations of claim 23, the rejection must be withdrawn.

The Action has directed Applicant to *In re Swinehart*, 169 USPQ 226. Applicants note that the entire citation, including the specifically cited page 229, are not on point. The claims of Swinehart were composition claims. The point of novelty in the Swinehart claims was a newly discovered function of the composition. As the action stated, "mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art." Emphasis added. As a preliminary matter, "identifying an individual in need of immune response" (claim 1) or "administering [the listed chemicals]" (claim 23) are not mere recitation of functional language, so Swinehart is irrelevant to the claims. Moreover, the Action cites Henderson's suggested administration of certain Table 2 disulfides for treatment of retroviral infections as the "things in the prior art". However, with regard to claim 1, Henderson's "things" do not inherently function, e.g., to identify an individual in need of immune modulation, identify individuals other than those with a retrovirus infection, or

administer the cited compounds to the identified individual. Further, with regard to claim 23, it can not reasonably be argued that administration of certain specific activating chemicals of Table 2 inherently functions to administer the five different listed compounds of the claim. The independent claims are distinguished over the prior art by more than a mere inherent function of the things in the prior art, so Swinehart is not controlling.

**Grassetti '364 does not inherently teach the claims.**

Grassetti '364 teaches, e.g., administration of 6,6'-dithiondinicotinic acid to cancer patients to improve their general physical condition (e.g., appetite) and to improve their feeling of well-being. As discussed above, although *Kropa* requires limitations of the preamble for completeness, the point is moot because the limitations have been amended into the body of the claim. As discussed above, Swinehart is not controlling because the rejected claims are distinguished over the prior art by more than a mere inherent function of the things in the prior art.

Not all limitations of the present claims are taught by '364. For example, with regard to independent claims 1 and 23, '364 does not teach at least: identifying an individual in need of immune response modulation, or modulating an immune response in need of modulation, e.g., wherein the immune response is a cellular response, a humoral response and an innate immune response.

Moreover, the claim limitations not found in '364 are not mere inherent functions of the things in the prior art, so Swinehart is not controlling. For example, identifying an individual in need of immune response modulation can not be considered a function inherently (i.e., necessarily) possessed by things (e.g., 6,6'-dithiondinicotinic acid) in '364.

Because the cited reference does not include all limitations of the independent claim, it is not anticipated, nor are any of the associated dependent claims anticipated.

With regard to claims 2, 5, 6, 10, 11, and 12, the Action fails to state a *prima facie* case. No attempt is made in the Action to allege a teaching of, e.g., identifying an individual in need of modulation of these particular immune responses in Grassetti '364. Indeed, no such teachings exist. Therefore additional reasons exist to withdraw the rejection of these dependent claims.

With regard to claims 20-22, the Action fails to even attempt to state a case, therefore, the rejections must be withdrawn.

Based on Examiner comments in the Interview of January 30, 2007, Applicants note that the Grassetti '364 treatment of post surgical patents with disulfides to induce a feeling of well-being does not inherently teach, e.g., identifying an individual in need of immune response modulation. For example, in many cases, the post surgical immune response of a patient can be appropriate, e.g., without need of modulation. Furthermore, identifying a post surgical patient in need of a psychological up-lift does not necessarily identify a patient in need of immune response modulation. For example, it is well known that surgical patients commonly experience distress due to many factors other than, e.g., an immune response imbalance. Therefore, Grassetti '364 does not inherently teach any of the present claims according to *Ex parte Levy*, 17 USPQ2d 1461, 1464, and *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

### CONCLUSION

In view of the foregoing, Applicants believes all claims now pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the claims are deemed not to be in condition for allowance after consideration of this Response, a telephone interview with the Examiner is hereby requested. Please telephone the undersigned at (510) 769-3510 to schedule an interview.

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Respectfully submitted,



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#### Attachments:

- 1) A transmittal sheet;
- 2) A Petition for a 1-month Extension; and,
- 3) A receipt indication postcard.